University of Pittsburgh

Mandatory Vaccine Program

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Sample Statements from BMBL 5th Edition

BSL-3 Special Practices (p.40):

*"Laboratory personnel must be provided medical surveillance and **offered** appropriate immunizations for agents handled or potentially present in the lab."*

Sample Statements from BMBL 5th Edition

ABSL-3 Special Practices (p.79):

"*Animal care staff, laboratory and support personnel must be provided a medical surveillance program as dictated by the risk assessment and* ***administered*** *appropriate immunizations for agents handled or potentially present…"*

Sample Statements from BMBL 5th Edition

Section VII Occupational Health (p.116):

"*Commercial vaccines should be **made available** to workers to provide protection against infectious agents to which they may be occupationally exposed.*"

Sample Statements from BMBL 5th Edition

Section VII Occupational Health (p.116):

"***If potential consequences of infection are substantial and the protective benefit from immunization is proven, acceptance of such immunization may be a condition for employment.***"

Historically at PITT

Lab-specific risk assessment *conducted by PI* regarding vaccination of workers:

a) Not recommended, therefore not offered

b) Recommended and offered; or

c) Mandatory

Historically at PITT

Expanded occupational health program, including health screening of all BSL-3 workers (2003)

Historically at PITT

Rabies Protection Program formalized (2004)

- Created four risk groups of personnel, and required vaccination/immunity for highest risk group.

Historically at PITT

Other Factors and Milestones

- Pitt RBL
- Expansion of select agent research
- Expansion of research with 'exotic' agents
- Appeals by the dean of the Graduate School for Public Health to adopt policies that promote/endorse vaccination
- OSHA/USDA Investigation (2008-2009)
- Continued PI demand to mandate vaccination

Vaccination Forum (March 2010)

Stakeholders present:

- Investigators
- Infectious Disease experts
- Vaccine experts
- Veterinarians
- RO/AROs
- Office of the General Counsel
- Human Resources
- Office of the Provost
- Occupational Health
- EH&S

Vaccination Forum

Pitt Survey of 10 peer institutions regarding Mandatory Vaccines:

7 Voluntary

2 Mandated in specific settings, but no policy

1 Mandated for JEV with a written policy

Vaccination Forum Outcomes

I. No broad "Vaccination Policy" adopted

II. Pathogen-specific guideline to be developed and approved by

1) PI
2) University Biohazards Committee
3) EH&S Director
4) General Counsel

Vaccination Forum Outcomes

III. Pathogen-Specific Risk Analysis by PI, EH&S and Biohazards Committee to include:

- Case fatality rate
- Endemic to region
- Efficacy of vaccine
- How the pathogen is manipulated (e.g. *in vivo*, rDNA…)

Vaccination Forum Outcomes

IV. Selection of "high risk" pathogens used at Pitt that have an FDA-approved vaccination

1. Japanese Encephalitis Virus
2. Yellow Fever Virus
3. *Bacillus anthracis*
4. *Neisseria meningitidis*
5. Rabies Virus
6. Vaccinia Virus strains
7. Influenza Virus strains
8. H1N1 Influenza

Vaccination Forum Outcomes

V. General Scope of Personnel Impacted by a Mandatory Vaccine Requirement:

- Vaccines are mandated only for those *individuals* with direct manipulation of infectious agent or infected animal
- Vaccination is not an "entry requirement"
- Visitors/non-employees must follow Pitt's rules

Vaccination Forum Outcomes

VI. Staff medically contra-indicated for a vaccine ?

A: Develop a support network for departments

Human Resources (staff)

Provost's Office (faculty)

Occupational Health Services

EH&S

Office of the General Counsel

Vaccination Forum Outcomes

VII. Proof of immunity (i.e. titers) not required post-vaccination

VIII. No work practice controls or precautions would be reduced

Administrative Considerations

- Identify positions and personnel
- Notification of impacted staff
- Length of implementation period (30-60 days)
- Alter Job Descriptions of impacted staff

Administrative Considerations

Job Description language

"The applicant will be performing [summarize tasks] with [list agent] and other pathogens. Proper handling of this infectious organism, [list agent] according to the laboratory biosafety manual is critical. Any error in handling could result in infection and serious illness or death. Therefore, the applicant must receive a vaccine for [list agent] prior to handling [list agent].

Administrative Considerations

- Who Pays?

  A: Costs borne by department of individual receiving the vaccination

Administrative Considerations

- Specialized Consent Form for Mandatory Vaccination

- Prioritize the 8 “high-risk” pathogens
  - Yellow Fever Virus and JEV assessed first

Executive Meeting (Sept 2010)

Leadership Questions:

- Is the disease fatal?
- Is the disease spread person-to-person?
- Are we doing enough without this mandate?
- WHAT DO THE RESEARCHERS WANT TO DO?

Vaccination Program for High Risk Pathogens at PITT

Pathogen	Biosafety Level	Current University Vaccination Guideline	Date Approved
Japanese Encephalitis Virus	BSL-3/ABSL-3	**Required**	11/16/2010
Yellow Fever Virus	BSL-3/ABSL-3	**Required**	11/16/2010
Neisseria meningitidis	BSL-2/ABSL-2	**Required**	12/17/2010
Bacillus anthracis	BSL-2/ABSL-2	Low Risk: Available, but not recommended	02/15/2011
	BSL-3/ABSL-3	High Risk: **Required**	
Rabies Virus	BSL-2/ABSL-2	Continuous Risk: **Required** + check titer every 6 months	02/15/2011
		Frequent Risk: **Required** + check titer every 2 years	
		Infrequent Risk: Offered	
		Rare Risk: Available but not recommended	
Vaccinia Virus	BSL-2/ABSL-2	Offered, recommended or not recommended: dependant on strain in use and results of required medical screening	02/15/2011
H1N1 Influenza Virus*	BSL-2/ABSL-2	Recommended	06/21/2011
Influenza Virus	BSL-2/ABSL-2 or BSL-3/ABSL-3	Recommended	06/21/2011

Pathogen-Specific Considerations

JEV

- Not endemic to US
- 30,000 annual cases
- Case fatality rate = 20%
- Neurological sequelae = 50%
- Effective vaccine
- ehs.pitt.edu/assets/docs/JEVSOP.pdf

YFV

- Not endemic to US
- 200,000 annual cases
- Case fatality rate = 20%
- Effective vaccine with persistent immunity (35 yrs)
- ehs.pitt.edu/assets/docs/YFVSOP.pdf

Pathogen-Specific Considerations

N. meningitidis

- 16 fatal LAI identified in informal literature search by Pitt
- 15% case fatality rate with treatment
- 15% of survivors have permanent sequelae
- Over 2,000 cases annually in US (endemic)
- Vaccine not 100% effective and not protective of serogroup B

Pathogen-Specific Considerations

B. anthracis

- Vaccination mandated for high risk tasks with virulent strains
- Considered protected 3 weeks after 3rd dose of the 5-dose regimen

Rabies Virus

- Vaccination mandated for two personnel categories
  - continuous risk (contact with purposely infected animals)
  - frequent risk (contact with wild or pre-quarantine animals known to harbor rabies)

Pathogen-Specific Considerations

Vaccinia Virus

- Health screening required
- Vaccination mandate is strain dependent

Pathogen-Specific Considerations

Influenza Strains

- Influenza endemic in US
- Vaccine not 'targeted' to specific strains being studied
- Immunity may not be conferred long-term
- Vaccination highly recommended NOT mandated

Results to Date

- 55 persons vaccinated under this new guidance
- One individual medically contra-indicated for vaccination
- No individual has formally challenged a mandatory vaccination

Conclusions

- The University of Pittsburgh seeks to be an advocate for vaccinations
- Mandating certain vaccinations serves the best interests of the worker, the investigator and the University
- A pathogen-specific risk analysis achieving a consensus of the investigator and the administration can successfully mandate a vaccine for workers